(3) ''Guidance on 510(k) Submissions for Keratoprostheses.''

[65 FR 17147, Mar. 31, 2000]

§ 886.3600 Intraocular lens.

(a) *Identification.* An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.3800 Scleral shell.

(a) *Identification.* A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 63 FR 59230, Nov. 3, 1998]

§ 886.3920 Aqueous shunt.

(a) *Identification.* An aqueous shunt is an implantable device intended to reduce intraocular pressure in the anterior chamber of the eye in patients with neovascular glaucoma or with glaucoma when medical and conventional surgical treatments have failed.

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(2) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),'' and

(3) ''Aqueous Shunts—510(k) Submissions.''

[65 FR 17147, Mar. 31, 2000, as amended at 66 FR 18542, Apr. 10, 2001]

Subpart E—Surgical Devices

§ 886.4070 Powered corneal burr.

(a) *Identification.* A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool intended to remove rust rings from the cornea of the eye.

(b) *Classification.* Class I (general controls). When intended only for rust ring removal, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[55 FR 48443, Nov. 20, 1990; 55 FR 51799, Dec. 17, 1990, as amended at 65 FR 2321, Jan. 14, 2000]

§ 886.4100 Radiofrequency electrosurgical cautery apparatus.

(a) *Identification.* A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.

(b) *Classification.* Class II.

§ 886.4115 Thermal cautery unit.

(a) *Identification.* A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) *Classification.* Class II.

§ 886.4150 Vitreous aspiration and cutting instrument.

(a) *Identification.* A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.

(b) *Classification.* Class II.

§ 886.4170 Cryophthalmic unit.

(a) *Identification.* A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

(b) *Classification.* Class II.

§ 886.4230 Ophthalmic knife test drum.

(a) *Identification.* An ophthalmic knife test drum is a device intended to test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 66 FR 38813, July 25, 2001]

§ 886.4250 Ophthalmic electrolysis unit.

(a) *Identification.* An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38813, July 25, 2001]

§ 886.4270 Intraocular gas.

(a) *Identification.* An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4275 Intraocular fluid.

(a) *Identification.* An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4280 Intraocular pressure measuring device.

(a) *Identification.* An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4300 Intraocular lens guide.

(a) *Identification.* An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.

(b) *Classification.* Class I (general controls). Except when used as folders or injectors for soft or foldable intraocular lenses, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 65 FR 2321, 2000]

§ 886.4335 Operating headlamp.

(a) *Identification.* An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Classification.* Class I for the battery-powered device. Class II for the